REMARKS/ARGUMENTS

This amendment and response is submitted in response to the Office Action dated October 22, 2003. After entry of this amendment claims 1-18, 20-31, 33 and 35 will be pending in the Application. Claims 5, 11, 21, and 31, have been amended. Claim 34 has been cancelled. New dependent claims 36-39 have been added. Basis for new claims 36-39 can be found on page 16, lines 10-25 of the application as originally filed. Reconsideration and allowance is respectfully requested in view of the amendments made and the remarks made below.

The specification has been amended to insert the related application data. Basis for this amendment can be found in the Declaration and Power of Attorney filed with the application.

1. Co-pending U.S. Patent Applications

The applicant would like to call to the attention of the Examiner the existence of the following co-pending U.S. patent applications for the Examiner's consideration:

A. U.S. Patent Application no. 10/649,529, filed on August 27, 2003.

B. U.S. Patent Application no. 09/874,580, filed on June 5, 2001.

C. U.S. Patent Application no. 09/858,816, filed on May 16, 2001.

D. U.S. Patent Application no. 10/010,250, filed on November 7, 2001.

E. U.S. Patent Application no. 10/342,536, filed on January 15, 2003.

F. U.S. Patent Application no. 10/718,950, filed on November 21, 2003.

2. Allowable Subject Matter

The applicant hereby acknowledges the Examiner's indication of allowable subject matter with appreciation. More specifically, the Examiner has allowed claims 7-10 and 12-14.

Claim 11 was indicated as allowable if the objection is overcome. Applicant believes that the objection has been overcome, as discussed below, and earnestly requests notice to that effect.

Claims 21-30 were indicated as allowable so long as the claims are rewritten to remove any § 112 issues. Applicant has amended claim 21 to remove any § 112 issues. Applicant

believes that claims 21-30 are in condition for allowance and earnestly requests notice to that effect.

Claim 34 was objected to as being allowable but dependent upon a rejected base claim. Applicant has incorporated claim 34 into independent claim 31. Applicant believes that amended claim 31 is now in condition for allowance. Claims 33 and 35 depend from claim 31 and are therefore allowable due to their dependence on a now allowable base claim. Accordingly, applicant believes that claims 31, 33, and 35 are now in condition for allowance.

3. Claim Objections

Claim 11 was objected to due to a typographical error. Specifically, the Examiner requested that the applicant change "house" to --housed-- in line 4 of claim 11. Applicant has reviewed the clean copy of claim 11 submitted in the Amendment filed on December 9, 2002, and believes that the word "housed" appears in this version of claim 11 and thus that there is no typographical error to be correct. There is a typographical error in the redline version of claim 11 that was attached to the Amendment filed December 9, 2002, but it is believed that the clean copy is the officially entered version of claim 11 and thus no correction is needed. Should the Examiner disagree with this position, the applicant will be happy to comply with any future request of the Examiner regarding this issue. Applicant believes claim 11 is in condition for allowance and earnestly requests notice to that effect.

Applicant has additionally amended claim 5 to place the word, "the" in front of the term "radioactive source" in line 5 of claim 5 to correct a minor typographical error in original claim 5.

4. The 35 U.S.C. §112 Second Paragraph Rejections

Claims 21-30 were rejected in the Office Action under 35 USC §112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission accounting to a gap between the necessary structural connection.

In particular, the rejection states that in claim 21, lines 8-11, that, "insufficient structure is recited to support the functional language "for releasably attaching the catheter attachment to the

catheter at or near the distal end of the catheter." In response, Applicant has amended claim 21 to remove the language "wherein the catheter attachment includes structure which cooperates with structure on a catheter" and has replaced it with "attachment means." Support for this amendment can be found on page 5, lines 10-22 in the specification.

Applicant believes that this should remove the rejection since it is permissible to claim structure in "means-plus-function" format under 35 U.S.C. §112, ¶6, and the specification and drawings describe those structural components necessary to perform the function of releasably attaching the catheter attachment to the catheter at or near the distal end of the catheter, and the skilled person is aware of many conventional structures for providing snap-fits and/or interference fits, within the scope of the skilled person's common general knowledge. The amendment of claim 21 also remedies the § 112 issue in claims 22-30 as well. Applicant believes claims 21-30 are now in condition for allowance and earnestly requests Examiner's indication thereof.

5. The 35 USC § 103(a) Rejections

Claims 1-5 have been rejected under 35 U.S.C. 103 (a) as being unpatentable over Hess (U.S. Patent No. 5,302,168) in view of Dake et al. (U.S. Patent No. 5, 199,939). Claims 1-5 have also been rejected under 35 U.S.C. 103 (a) as being unpatentable over Hess in view of Dake et al. and further in view of Krasnicki et al. (U.S. Patent No. 4,676,229).

Hess discloses a device for radiation treatment including an angioplasty balloon 36 provided with radioactive dose means in the form of radioactive elements 38 attached thereto, as shown in Fig. 2 of Hess. The rejection, on page 3, takes the position that; "it is well known to attach one body to the surface of another body utilizing an adhesive of sufficient bond strength to prevent subsequent separation of the bodies." The rejection further states, on page 3, that, "it would have been obvious to have attached the radioactive source in the device of the combination of Hess and Dake et al. by bonding to the surface of the Hess-Dake et al. catheter by utilizing an adhesive of sufficient bond strength to prevent subsequent separation of the radioactive source from the catheter body during use of the Hess-Dake et al. catheter for treatment of restenosis."

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 265 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine,* 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

The rejection fails to provide any evidence that either Hess or Dake et al. teaches bonding. In fact, the Examiner noted on page 3 of the Office Action that, "Hess does not disclose that radioactive source 38 is attached to balloon 36 by bonding." The Examiner has merely stated that such bonding is "well known." However, this is insufficient evidence to support a rejection. Neither Hess nor Dake et al. provide any teaching of bonding a radioactive source to a surface of the distal section of the catheter body and the Examiner has provided no evidence that bonding radioactive material to a surface of the distal section of a catheter body with sufficient bond strength that under normal conditions of use of the catheter, the radioactive source will not detach from the catheter body is well-known.

It is requested that the Examiner substantiate this position pursuant to MPEP §2144.03(C). Applicant notes that devices for insertion into the body employing radioactive material generally include a biocompatible coating on the outer surface thereof to prevent the radioactive material from detaching from the device during normal conditions of use. Dake et al., for example, advocates locating the radioactive material inside the distal end of the catheter body. See e.g. Fig. 9 of Dake et al. Carden, Jr. (U.S. Patent No. 5,405,309) also emphasizes the need for an outer, biocompatible coating over the radioactive material to prevent contact of the radioactive material with bodily fluids. See e.g. col. 7, lines 32-38 of Carden, Jr. In view of these facts, the Examiner's position that it is well-known to bond radioactive material with sufficient bond strength that under normal conditions of use of the catheter, the radioactive source will not detach from the catheter body, is questionable and should be substantiated with evidence pursuant to MPEP §2144.03(C).

Moreover, in advocating the use of an adhesive, the Examiner takes the position that it would be obvious to use an adhesive having sufficient bond strength to bond the radioactive material to the substrate. However, this oversimplifies the problem faced by the skilled person.

Such an adhesive would additionally have to be biocompatible, the bond strength and chemical stability of the adhesive would have to be maintained in contact with the various bodily fluids that may be encountered in use, and the adhesive would have to bond a metal (the radioactive material) to a plastic (the catheter), a type of bonding for which few adhesives are suitable. Also, the adhesive must be radiation-stable, i.e. not degrade when exposed to radiation. Many common materials are not radiation-stable and thus this presents an additional problem. Thus, there are many difficult problems to be faced in adhering a radioactive material to a catheter body with sufficient bond strength that under normal conditions of use of the catheter, the radioactive source will not detach from the catheter body. As a result, it is not obvious how to accomplish this task using only information well-known to a skilled person.

For these reasons, applicant respectfully requests that the rejection of claims 1-5 under 35 U.S.C. §103(a) over Hess in view of Dake et al., be withdrawn.

The Office Action additionally rejected claims 1-5 under Hess in view of Dake et al. and further in view of Krasnicki et al. The Office Action utilizes Krasnicki to provide support for bonding of a radioactive source to a surface of the distal section of the catheter body. However, Applicant respectfully submits that Krasnicki et al. does not provide the missing teaching necessitated by the combination of Hess in view of Dake et al.

Krasnicki et al. provides teaching of bonding a filament to the outside of a tubular substrate using epoxy cement. Applicant contends that using epoxy cement to glue a filament to the surface of the tube is not the same as bonding a radioactive source to the surface of catheter body. Attaching the filament does not present the same issues as bonding a radioactive source to the surface of a catheter, such as the stability of the adhesive when exposed to radiation, what will happen to the adhesive when exposed to body fluids, or even whether the adhesive is biocompatible. Krasnicki et al. is not concerned with any of these issues since Krasnicki et al. coats the tube and filament with a coating to help strengthen the overall integrity of the structure. See col. 4, lines 1-17. From this, it can be concluded that Krasnicki et al. is convinced that the structural integrity of the filament glued to the tube is insufficient to be relied on in the body and thus that a further coating must be applied to solve this problem. From this it is also apparent that the adhesive of Krasnicki et al. will not be exposed to the body since it will be covered byteh coating and thus it need not be biocompatible nor is degradation or alteration by bodily fluids a

concern in the Krasnick et al. device since the adhesive will be protected from exposure to bodily fluids by the outer coating.

Finally, the usage of epoxy cement for bonding a filament to a tube is not analogous to the methods used for bonding a radioactive source to the surface of a catheter. Rather, The radioactive source must be bonded using a suitable method such as, for example, electroless plating, to bond the radioactive source to the surface of the catheter. Other examples of suitable bonding methods are disclosed on page 7 of the specification.

Krasnicki et al. is not concerned with the bonding of radioactive sources to catheters, and Krasnicki et al. admits that the filament glued to the tube has insufficient structural integrity and thus adds an outer coating to address this problem. Thus, Krasnicki et al. does not provide the necessary teachings to cure the deficiencies found in Hess and Dake et al.

Applicant respectfully submits that neither the Hess in view of Dake et al. rejection under 35 U.S.C. §103(a), nor the Hess in view of Dake et al. and further in view of Krasnicki et al. rejection under 35 U.S.C. §103(a), provide the required teaching of bonding a radioactive source to the surface of a catheter. Applicant therefore respectfully requests that the rejections be removed and claims 1-5 be allowed.

Applicant further submits that claim 6 should also be allowed by virtue of its dependence on independent claim 1 and further in view of the fact that Carden, Jr. (U.S. Patent no. 5,405,309) does not cure the deficiencies of Hess, Dake et al. and Krasnicki et al. discussed above.

Claims 15 and 16 have been rejected under 35 USC 103(a) as being unpatentable over Liprie (U.S. Patent No. 5,282,781) in view of Hess, and further in view of Dake et al.

Liprie discloses a device including a source wire 10 with a plug 27 to provide access to the cavity wherein radioactive core 25 is placed (shown in Fig. 1). Hess discloses a device 10 having a distal end 18 with tip 20 and a wire wound housing 22 with a sheath 24 that is retracted in order to expose a window cut 32 which permits exposure of the radioactive source 30. The rejection argues that it would have been obvious to one of ordinary skill in the art at the time the invention was made, "to have provided a retractable sheath in the device of Liprie for radiation shielding as taught by Hess." Applicant contends that one of ordinary skill in the art would not have looked to Hess since having a retractable shield in Liprie would have been undesirable.

Liprie's device is designed so that radioactive core 25 is within hollow tubing 12. As the rejection points out, on page 5, "carrier 10 is placed within conventional tubing as a protective sheath for radiation treatment of a body." In other words, since the hollow tubing 12 of Liprie is the "sheath," it would have to be the portion of Liprie's device that is retractable. However, this is not desirable in Liprie's device. Liprie's device is designed so that the radioactive source is effective without removal from the hollow tubing 12. Indeed, preventing the exposure of the radioactive core 25 to the body is the purpose of hollow tubing 12. One of the reasons for the structure of Liprie's device is due to the brittleness of the core that tends to cause flaking and the high dosage of the source. See col. 3, lines 52-54, and lines 65-68. The radioactive core 25 intended for use in Liprie's device would therefore be too strong and too brittle to permit open exposure. Retracting a portion of the sheath would thus be undesirable in the device of Liprie for at least these reasons. Furthermore, open exposure of the radioactive source used for Liprie's device may be too strong since Liprie's source is designed to compensate for shielding of radiation by the material of hollow tube 12. Also, direct exposure of the Liprie source to the body is undesirable since, as Liprie points out, it is prone to flaking thus increasing the risk that radioactive material may be separated from the Liprie device and be transported to other portions of the body.

Accordingly, since the proposed modification of Liprie with the retractable sheath of Hess renders Liprie unsatisfactory, in many ways, for its intended purpose, as discussed above, it cannot support a rejection under 35 U.S.C. §103(a). See e.g. MPEP 2143.01 and *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Applicant earnestly requests that the rejection of claim 15 be withdraw. Applicant submits that the rejection of claims 16-18, and 20 should be withdrawn as well due to their dependence on claim 15.

6. Conclusion

Applicant has made an earnest effort to place this application in condition for allowance. If the Examiner feels that a telephone interview would expedite prosecution of this patent application, the Examiner is respectfully invited to telephone the undersigned at 215-599-0600.

Respectfully submitted,

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